APR 1 1 2011

510(k) Summary

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Sponsor	Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430
Contact Person	Karen Ariemma Project Manager, Regulatory Affairs/Regulatory Compliance Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5718
Date Prepared:	April 8, 2011
Proprietary Name:	Tritanium® Peri-Apatite™ Acetabular Shell System
Common Name:	Artificial Hip Replacement Components - Acetabular

Classification Name:
21 CFR §888.3358: Hip joint metal/polymer/metal semi-constrained and porous-coated uncemented prosthesis

21 CFR §888.3310: Hip joint metal/polymer constrained cemented or uncemented prosthesis.

21 CFR §888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis:

21 CFR §888.3360 - Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.

21 CFR §888.3350 - Hip joint metal/polymer semi-constrained cemented prosthesis

Product Codes: LPH, MEH, LZO, KWZ, LWJ and JDI

Legally Marketed Device to Which Substantial Equivalence is Claimed:
Howmedica Osteonics Tritanium Acetabular Shell System: K081171
Howmedica Osteonics Vitalock Solid Back Acetabular Shell with Peri-Apatite: K971206
Landos Inc. Corail Stem: K953111
Aesculap BiContact Hip System with μ-CaP K043079
Smith& Nephew, Smith & Nephew Hip Systems with HA Coating: K090982.

Device Description: The Tritanium® Peri-Apatite ™ acetabular shells are available in both solid backed and cluster screw-hole designs for cementless, biologic fixation. The Howmedica Osteonics Tritanium® Peri-Apatite™ Acetabular Shell consists of a hemispherical, metallic acetabular shell with a Tritanium® (CPTi) coating referred to as a Particle Sintered Foam (PSF) coating with an overlying Peri-Apatite coating (precipitated calcium phosphate coating). The Peri-Apatite™ coating process is identical to that cleared in K971206 but to a greater thickness range of 35-75 microns. The Tritanium® CPTi PSF coating originally manufactured from material conforming to ASTM F67 was modified to conform to ASTM F1580. The dual coating (Peri-Apatite™ overlying the PSF coating) at

the thickest specification met the definition of a porous coating per 21 CFR 888.3358 with no additional claims over biologic fixation. The dome hole plugs are optional devices which are available to seal the Howmedica Osteonics Tritanium® Acetabular Shells. The plugs are to be threaded into the dome holes of the shell.

The shells will be available in sizes 44-72 mm outside diameter (OD) in 2 mm increments. The acetabular shells are forged from Ti-6Al-4V alloy per ASTM F136; the Tritanium® coating is fabricated from Commercially Pure Titanium per ASTM F1580; and the Peri-Apatite™ coating is a precipitated calcium phosphate coating per ASTM F-1609.

The Tritanium® Peri-Apatite™ Acetabular Shells are compatible with polyethylene Trident® inserts, constrained liners and modular dual mobility liners. The subject shells have an identical insert locking mechanism to that employed with compatible Tritanium acetabular shell system predicates. All shells are single use devices. The outer surface of the acetabular shell has the identical geometry as the predicate Tritanium® Acetabular Shell System determined substantially equivalent via 510(k) K081171.

Intended Use: The Tritanium® Peri-Apatite™ Acetabular Shell is a sterile, single-use device intended for use in primary and revision total hip arthroplasty to alleviate pain and restore function.

Indications:

The indications for use of the total hip replacement prostheses include:

1. Painful, disabling joint disease of the hip resulting from: non-inflammatory degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis, or late stage avascular necrosis.
2. Revision of previous failed femoral head replacement, shell arthroplasty or other procedure.
3. Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
4. Where bone stock is of poor bone quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Additional indications for use when using constrained liners: The device is indicated for use as a component of a total hip prosthesis in primary and revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intra-operative instability.

Additional indications for use when using modular dual mobility (MDM) liners: The device is indicated for use as a component of a total hip prosthesis and include:

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. Rheumatoid arthritis;
3. Correction of functional deformity;
4. Revision procedures where other treatments or devices have failed;
5. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; and
6. Dislocation risks

The MDM liners are intended for cementless use only. The acetabular shell is intended for cementless use only.

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Summary of Technologies: The technology characteristics are the same basic principles as the predicates with minor differences occurring in the material of Tritanium underlying surface and the Peri-Apatite thickness.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. Non-clinical testing was provided as outlined in the FDA Guidance Document entitled "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement (28 April 1994)" for the underlying Tritanium surface which included additional testing on the CPTi Tritanium conforming to ASTM F1580 in terms of static tensile, static shear and shear fatigue bond strength testing. The dual coating/surface was characterized per the FDA Guidance document entitled "510(k) Information Needed for Hydroxyapatite Coated Orthopaedic Implants (February 20, 1997)." All characterization parameters on the final dual coating/surface were provided. The NIST SRM 2910(a) material was used as a comparator for the Xray diffraction, dissolution rate and solubility product parameters. The dual coating/surface underwent additional characterization to demonstrate that the definition of porosity was met per 21 CFR 888.3358 at the thickest specification. Additionally, four-point bend fatiguing, abrasion, and fatigue strength of the subject acetabular shell were performed. Third body wear information was provided to address the theoretical risk. All of the observed results indicate that the subject Tritanium® Peri-Apatite™ Acetabular Shell System is substantially equivalent to devices currently cleared for marketing.

Clinical Testing: None provided as a basis for substantial equivalence.

Conclusion: The Tritanium® Peri-Apatite™ Acetabular Shell System is substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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% Ms. Karen Ariemma, RAC
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Regulatory Compliance
325 Corporate Drive
Mahwah, New Jersey 07430

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Re: K101072
Trade/Device Name: Tritanium® Peri-Apatite™ Acetabular Shell System
(Tritanium® Peri-Apatite™ Acetabular Solid-backed Shell and
Tritanium® Peri-Apatite™ Acetabular Cluster Screw-hole Shell)
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, MEH, LZO, KWZ, LWJ, JDI
Dated: March 31, 2011
Received: April 04, 2011

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101072

Device Name: Tritanium® Peri-Apatite™ Acetabular Shell System

Indications for Use:

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1. Painful, disabling joint disease of the hip resulting from: non-inflammatory degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis, or late stage avascular necrosis.
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The MDM liners are intended for cementless use only. The acetabular shell is intended for cementless use only.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101072